

Sir:

PATENT Attorney Docket 053529-5007-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Berkley Lynch et al.)
Application No. 10/537,512) Group Art Unit: <i>Unassigned</i>
Filing Date: June 3, 2005) Examiner: Unassigned
For: Methods for the Identification of Agents for the Treatment of Seizures, Neurological Diseases, Endocrinopathies and Hormonal Diseases))))
United States Patent and Trademark Office Customer Service Window, Mail Stop Amendmen Randolph Building 401 Dulany Street Alexandria, VA 22314	ıt

<u>INFORMATION DISCLOSURE STATEMENT</u> UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants petition the Examiner to consider this Information Disclosure Statement and documents listed on the attached Form PTO-1449. To the best of the undersigned's knowledge, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced Application. Accordingly, Applicants do not believe a fee is due for filing this Information Disclosure Statement.

The present application is a U.S. National Phase Application of International Application No. PCT/US2003/038122, filed December 2, 2003 and published June 17, 2004 as WO 2004/051222 A2. It is cited on Form PTO-1449 as Document 5.

Applicants wish to bring the following related United States pending patent applications to the Examiner's attention:

U.S. Patent Application 10/308,163, filed December 3, 2002, and published as U.S. published application no. 2004/0106147 on June 3, 2004; and

U.S. Patent Application 10/725,189, filed December 2, 2003, and published as U.S. published application no. 2004/0204388 on October 14, 2004.

With the exception of published U.S. Applications, copies of the listed documents are attached. Applicants respectfully request that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If it should be determined that the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. §1.136(a)(3).

Dated: March 2, 2006 Morgan, Lewis & Bockius LLP Customer No. 09629 1111 Pennsylvania Avenue Washington, D.C. 20004 202-739-3000 Respectfully submitted,

Morgan, Lewis & Bockius LLP

Registration No. 45,397

INFORMATION DISCLOSURE CITATION			Attorney Docket No. 053529-5007-02		Application No. 10/537,512			
Use several sheets if necessary)				Applicants: Berkley Lynch et al.				
MAR 0 2 2006 PTO Form 1449			Filing Date: June 3, 2005		05	Group Art Unit: Unassigned		
Initial			U.S. PA	TENT DOCUN	MENTS			
Initial	AUG	Document No.	Date	N	ame	Class	Sub-Class	Filing Date
	1.	US 2003/0009024 A1	01/09/2003	C	urtis	536	23.5	06/13/2002
	2.	US 2002/0142383 A1	10/03/2002	Merku	Merkulov et al. 435		69.1	04/02/2001
			FOREIGN	PATENT DOC	TIMENTS			
		Document No.	Date		untry	Class	Sub-Class	Translation
	3.	WO 01/62726 A2	08/30/2001		/IPO	Cluss	Sub-Class	11 ansiation
	4.	WO 01/62726 A3	08/30/2001		/IPO	 	1	
	5.	WO 2004/051222 A2	06/17/2004		/IPO	 		
		11 O 200 11 O 31222 112	00/17/2004		110	1		
		1100					1	
		OTHER DO	CUMENTS (Includ	ing Author, Ti	tle. Date. Per	tinent Pa	res etc)	
	6.	Bajjalieh, S.M., et al.,	"SV2. a brain synapt	ic vesicle prote	in homologous	s to bacter	rial transporte	ers " Science 257:1271
		1273, American Associ	ation for the Advanc	ement of Science	ce Washingto	n DC LIS	A (Anomet 10	002\
	7.	Bajjalieh, S.M., et al.,	"Brain contains two	forms of synant	ic vesicle prot	ein 2 " Pr	oc Natl Aco	d Sci 1/54 90:2150
		2154, National Academ	v of Sciences. Wash	ington DC. US	A (March 199)	3)	oc. Nan. Aca	a. bei. Obh 90.2130-
	8.	Bajjalieh, S.M., et al., "					Isoforms "	I Naurosai 14:5222
		5235, The Society for N	Jeuroscience, Washin	igton DC. USA	(September 1	994)	, 1301011113, 2	1. IVEUI OSCI. 14.52254
	9.	Buckley, K. and R.B. K	elly, "Identification	of a Transmeml	orane Glycopr	otein Spec	cific for Secr	etory Vesicles of
		Neural and Endocrine (Cells," J. Cell Biol. 10	00:1284-1294.	The Rockefell	er Univers	sity Press Ne	w York NY USA
		(April 1985)	,	· · · · · · · · · · · · · · · · · · ·			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	101
	10.	Crowder, K.M., et al., '	'Abnormal neurotran	smission in mic	e lacking syna	aptic vesic	le protein 2A	(SV2A)" Proc Natl
		Acad. Sci. USA 96:1526	68-15273, National A	cademy of Scie	ences. Washin	gton DC.	USA (Decem	t (5 / 2/1), 1 / 00. 1/411.
	11.	Feany, M.B., et al., "Th	ne Synaptic Vesicle P	rotein SV2 is a	Novel Type o	f Transme	embrane Tran	sporter." Cell 70:861-
		867, Cell Press, Cambri	idge MA, USA (Sept	ember 1992)				.sporter, Cett 70.001-
	12.	Fuks, B., et al., "Locali	zation and photoaffir	ity labelling of	the levetirace	tam bindi	ng site in rat	brain and certain cell
		lines," Eur. J. Pharmac	ol. 478:11-19, Elsevi	er B.V., Amste	rdam. The Ne	therlands	(September 2	2003)
	13.	Hayashi, M., et al., "Sy	naptic Vesicle Prote	in SV2B, but N	ot SV2A, is P	redomina	ntly Expresse	d and Associated with
		Microvesicles in Rat Pi	nealocytes," J. Neuro	ochem. 71:356-3	365. Lippincot	tt-Raven P	ublishers. Ph	iladelphia PA LISA
		(July 1998)						-
	14.	Janz, R., et al., "SVOP,	an Evolutionarily Co	onserved Synap	tic Vesicle Pro	otein, Sug	gests Novel	Fransport Functions of
		Synaptic Vesicles," J. N	leurosci. 18:9269-92	81, The Society	for Neuroscie	ence, Was	hington DC.	USA (November 1998)
	15.	Janz, R., et al., "SV2A	and SV2B Function a	s Redundant C	a ²⁺ Regulators	in Neuro	transmitter R	elease." Neuron
		Janz, R., et al., "SV2A and SV2B Function as Redundant Ca ²⁺ Regulators in Neurotransmitter Release," Neuron 24:1003-1016, Cell Press, Cambridge MA, USA (December 1999)						
	16.	Janz, R., "Knockout Mi	ce and SV2 Synaptic	-Vesicle protein	ns," <i>University</i>	of Texas	Health Scien	ice Center at Houston
		Neuroscience Research	Center Newsletter 7:	1-8, Neuroscie	nce Research	Center, Ho	ouston TX, U	SA (2001)
	17.	Lynch B., et al., "The s	ynaptic vesicle protei	n SV2A is the l	oinding site fo	r the antie	pileptic drug	levetiracetam." Proc.
		Natl. Acad. Sci. USA 10	1:9861-9866, Nation	al Academy of	Sciences, Was	shington I	C, USA (Jui	ne, 2004)
	18.	Margineanu, D.G., and	H. Klitgaard, "Levet:	racetam: Mech	anisms of Act	ion," In: A	Intiepileptic I	Drugs, 5th Edition, pp.
		419-427, Levy, R.H., et	al. eds., Lippincott	Williams & Wi	lkins, Philadel	lphia PA, i	USA (June 2	002)
	19.	419-427, Levy, R.H., et al. eds., Lippincott Williams & Wilkins, Philadelphia PA, USA (June 2002) Noyer, M., et al., "The novel antiepileptic drug levetiracetam (ucb L059) appears to act via a specific binding site in						
		CNS membranes," Eur. J. Pharmacol. 286:137-146, Elsevier B.V., Amsterdam, The Netherlands (November 1995)						
Examiner			Date Co	onsidered				
				1.50		arm.		
examiner:	Initia	l if reference considered,	whether or not citat	ion is in conform	mance with M	PEP 609;	draw line thr	ough citation if not in
onformance and not considered. Include copy of this form with next communication to applicant.								

INFORMATION DISCLOSURE CITATION			Attorney Docket No. 053529-5007-02		Application No. 10/537,512				
Star.	42 N	se several sheets if necessary)	Applicants: Berkley Lynch et al.						
MAR 0 2 2006 W PTO Form 1449		Filing Date: June 3, 2005		Group Art Unit: Unassigned					
STEW & TR	ADEMA	U.S. PA	TENT DOCUMENTS						
Initial		Document No. Date	Name Class		Sub-Class Filing Date				
				-					
				.					
	Ι-		PATENT DOCUMENTS	Class	C. L. Cl	T			
		Document No. Date	Country	Class	Sub-Class	Translation			
	<u> </u>								
					_ 				
	20.	Pyle, R.A., et al., "Phosphorylation of Syna				otagmin " I Riol			
		Chem. 275:17195-17200, The American So (June, 2000)	ciety for Biochemistry and M	Iolecular E	Biology, Inc.,	Bethesda MD, USA			
	21.	Schivell, A.E., et al., "Isoform-specific, Cal	cium-regulated Interaction of	f the Synar	otic Vesicle F	Proteins SV2 and			
		Synaptotagmin," J. Biol. Chem. 271:27770-27775, The American Society for Biochemistry and Molecular Biology, Inc., Bethesda MD, USA (November 1996)							
	22.	Son, Y-J. et al., "The Synaptic Vesicle Protein SV2 is Complexed with an α5-Containing Laminin on the Nerve Terminal Surface," J. Biol. Chem. 275:451-460, The American Society for Biochemistry and Molecular Biology, Inc., Bethesda MD, USA (January 2000)							
	23.	Xu, T., and S.M. Bajjalieh, "SV2 modulates the size of the readily releasable pool of secretory vesicles," <i>Nat. Cell Biol.</i> 3:691-698, Macmillan Magazines Ltd., London, England (August 2001)							
	24.	Nagase, T., et al., "Prediction of the Coding Sequences of Unidentified Human Genes. XI. The Complete Sequences of 100 New cDNA Clones from Brain Which Code for Large Proteins in vitro," DNA Res. 5:277-286, Kazusa DNA							
2	25.	Research Institute and Universal Academy Press, Chiba, Japan (1998) Nagase, T., et al., "Genbank Accession 094841, KIAA0736 Human SV2," 2 pages, National Center for							
		Biotechnology Information, Bethesda MD,	USA (May 1, 1999)						
	20.	Li, C.H., et al., "β-Endorphin omission analogs: Dissociation of immunoreactivity from other biological activities," Proc. Natl. Acad. Sci. USA 77:3211-3214, National Academy of Sciences, Washington DC, USA (June 1980)							
	27.								
		88:156-165, Blackwell Scientific Publicatio	ns, Oxford, England (Septem	ber 1994)					
	28.	Skolnick, J., and J.S. Fetrow, "From genes to protein structure and function: novel applications of computational approaches in the genomic era," <i>Trends Biotechnol.</i> 18:34-39, Elsevier Science Ltd., Amsterdam, The Netherlands (January 2000)							
		(Sanuary 2000)							
				-	-				
Examiner		Date C	onsidered						
Examiner:	Initial	if reference considered, whether or not citat not considered. Include copy of this form wi	ion is in conformance with M	1PEP 609;	draw line th	rough citation if not in			